DEVELOPMENT AND PHYSICAL CHARACTERIZATION OF A NOVEL BIODEGRADABLE SCAFFOLD WITH GROWTH FACTORS AND NANO PARTICLES

SHORT SYNOPSIS

Submitted in partial fulfillment of the requirement of the degree of

DOCTOR OF PHILOSOPHY

to

Manav Rachna International Institute of Research and Studies

(Deemed to be University)

by

ALPA GUPTA

Registration number: 21/Ph.D/030

Under the supervision of

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I hereby declare that the short synopsis " **DEVELOPMENT AND PHYSICAL CHARACTERIZATION OF A NOVEL BIODEGRADABLE SCAFFOLD WITH GROWTH FACTORS AND NANOPARTICLES**" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Conservative Dentistry and Endodontics under Faculty of Dental Studies of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2021-22. It is a bona fide record of original work carried out under the supervision of Dr. Arundeep Singh, Dr. Vivek Aggarwal and Dr. Shakila Mahesh has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

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ABSTRACT

Concentrated Growth factor (CGF). CGF is an advanced 2nd generation platelet concentrates with strengthened fibrin matrix containing enhanced growth factors, platelets, leukocytes and CD34+ hematopoietic stem cells. The application of compressed CGF to stimulate bone and tissue regeneration because of its enriched autologous growth factors can be used as a barrier membrane or a bioactive and biodegradable scaffold as an alternate to commonly used collagen membrane. The compressed CGF as ascaffold will help to demonstrate in the stimulation of bone repair, soft tissue regeneration, support physiological wound healing mechanisms.

In addition to the bioactive platelets aggregates for dental and medical applications, metal – derived nanoparticles have also been extensively studied and used for its therapeutic properties. Silver nanoparticles (SNP) are biocompatible with efficient antimicrobial effects. Hence the aim of the study is to look forward for nanoparticles incorporated host derived scaffold so that further clinical application can be make possible with this new scaffold.

Key words: concentrated growth factor, platelet rich fibrin. Nanoparticles, hydroxyapatite, antimicrobial

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INTRODUCTION

Developing bioactive surgical additives with regenerative properties to enhance the healing process by reducing the inflammation is of utmost importance in today's time. The role of bioactive surgical additives such as platelets and its concentrates in healing mechanism by release of array of growth factors, cytokines to stimulate healing, proliferation, differentiation and cellular growth upon activationis well studied and clinically documented (Anitua, Sánchez, Orive, & Andía, 2007). Different types of platelets concentrates such as autologous platelet rich growth factors (PRGF), platelet rich plasma(PRP), and platelet rich fibrin (PRF) have been employed for surgical interventions locally to fasten the tissue regeneration and increase the speed of healing process in various dental conditions such as oral& maxillofacial surgeries, periodontal regeneration, sinus lift, gingival recession, perio-endo lesions, implant procedures, periapical endodontic surgeries and in medical conditions such as Osteoarthritis, sports injuries, avascular necrosis or osteonecrosis of the hip, diabetic foot ulcer and etc (Anitua et al., 2008; Anitua, Andia, Ardanza, Nurden, & Nurden, 2004; Qiao, Duan, Zhang, Chu, & Sun, 2016).

One of the latest advancements in bioactive surgical addictive family is the new autologous platelet concentrate with enriched growth factors named Concentrated Growth factor (CGF). CGF is an advanced 2nd generation platelet concentrates with strengthened fibrin matrix containing enhanced growthfactors, platelets, leukocytes and CD34+ hematopoietic stem cells. The difference in the revolution per minute (rpm) helps in the isolation of CGF with a large and dense fibrin rich in growth factors in comparison to PRP and PRF. The application of compressed CGF to stimulate bone and tissue regeneration because of its enriched autologous growth factors can be used as a barrier membrane or a bioactive and biodegradable scaffold as an alternate to commonly used collagen membrane. The compressed CGF as a scaffold will help to demonstrate in the stimulation of soft tissue regeneration, support physiological wound healing mechanisms (Kawase & Tanaka, 2017; Rodella et al., 2011;Upadhayaya, Arora, & Goyal, 2017).

CGF will function as a reservoir to deliver growth factors to the injury site and will act as a scaffolding bioactive material (Rodella et al., 2011; Upadhayaya et al., 2017). The ideal scaffold for bone defect repair, tissue regeneration and healing should possess mechanical and biological properties relevant to anatomical surgical site along with good handling, storage, antimicrobial and biological properties (*Lyophilization/Freeze Drying - An Review*, 2013). The intrinsic application of CGF as a membrane support is currently explored mainly in dentistry applications. The significant usage of CGF to accelerate tissue and bone regeneration and evaluation of effectiveness of CGF as scaffold or membrane support is still in its emerging phase and needs substantial scientific evidences to translate the research from bench to bedside.

In addition to the bioactive platelets aggregates for dental and medical applications, metal – derived nanoparticles have also been extensively studied and used for its therapeutic properties. These nanoparticles are highly versatile and biocompatible, with multiple functions and can be used fordiagnosis and in drug delivery tools for treatment of cancer and bacterial diseases (Kuchur

et al., 2020). In most cases, platelet aggregates are exposed to the oral cavity, and are prone to interference by various microorganisms where a large number of microorganisms may interfere with the treatment (Zhang et al.,2010). Addition of silver nano-particles (SNP) to the platelet concentrates will enhance antimicrobial abilities and, improve mechanical properties (Khorshidi, Haddadi, Raoofi, Badiee, & Dehghani Nazhvani, 2018). The study addresses on the formation of novel scaffold by the incorporation of Ag in a fresh CGF scaffold in a biocompatible limit to improve stiffness and antimicrobial properties along with the soft tissue and bone healing properties. The prepared novel product as compared to traditional one will possess improve mechanical and antimicrobial properties for immediate autologous use (Andia, Perez-Valle, Del Amo, & Maffulli, 2020; Horimizu et al., 2013). The incorporation of nano Ag particle in a fresh scaffold and its potential in bone tissue regeneration in periodontal lesions, implants & various oral maxillofacial surgeries and endodontic conditions with bone defects have not been researched globally. The novel scaffold incorporated with the nano- particles would also eliminate the expensive bone grafts, barrier membranes and is very cost effective. The synergistic application of Silver particles, a well-documented anti-bacterial/ microbial agent promoting wound healing makes our novel product a complete package with CGF.

LITERATURE REVIEW

Ahamed, M., Alsalhi, M. S., & Siddiqui, M. K. J. (2010) - identified the use of nanoparticles and nanotechnology in a wide arena of commercial products around the world. For instance, SNP are utilized in the fields of electronics, biosensing, clothing and food industries, paints, cosmetics including sunscreens, and medical devices. With such wide applications, there is concern over the risk for short- and long-term toxicity since manyin vitro studies suggest that they are toxic to various mammalian cells derived from liver,skin, lung, brain, vascular system and reproductive organs. Some of these studies have even shown that they can induce genes for DNA damage and human cell apoptosis at non-cytotoxic doses. In vivo studies in rats and mice have demonstrated that these particles can lead to toxic reactions in several organs including brain and they lead to malformations in non-mammalian model organisms. Mechanism for toxicity is related to the particles action on cell membranes, mitochondria and genetic material. The paper critically focused on adverse reactions of SNP's.

Masuki, H., Okudera, T., Watanebe, T., et al. (2016) - Various studies have been carried out to highlight PRF 's clinical applications but there is still controversy about the concentration of growth factors in PRF preparations that enhance healing and regeneration. Therefore, a comparative study was carried out to check the contents in PRP and its derivatives, suchas advanced PRF (A-PRF) and concentrated growth factors (CGF) and it was demonstrated that both the preparations had significant amount of growth factors with potential to stimulate periosteal cell proliferation. The data suggests that they can be used as both a scaffolding material and a reservoir for growth factors.

Qiao, J., Duan, J., Zhang, Y. (2016) – The purpose of the study was to investigate the effect of concentrated growth factors (CGFs) in human intrabony defect treatment. Probing depth, clinical attachment level and hard tissue fill were evaluated at baseline and 1 year post surgery. No differences in any of the investigated parameters were observed at baseline. A favorable increase of hard tissue fill was noted in CGFs + BPBM group compared with BPBM group ($p > 0.05$) at 1 year. It was observed that growth factors in CGFs were statistically higher than those in platelet poor plasma ($p < 0.001$). Addition of CGFs significantly improved clinical effectiveness of BPBM for intrabony defect treatment.

Khorshidi, H.,Haddadi, P., Raoofi, S. (2018) - The study compared the antibacterial, mechanical, and histologic characteristics of the L-PRF membrane before and after the addition of silver nanoparticles (SNP). The antibacterial efficacy of L-PRF and nanosilver-modified L-PRF was presented as Klebsiella pneumonia had growth on the L-PRF membrane after 12 hours. After 24 hours, Klebsiella pneumonia and Streptococcus viridans had growth on L-PRF and only Klebsiella

pneumonia had growth on SNP-L-PRF. The tensile strength and stiffness were significantly higher in the SNP-L-PRF. Precipitation of the SNPs was patchy in the outer layers and quite homogeneous in the inner core. The study concluded that modification of L-PRF with SNP improves the mechanical properties and antibacterial activity of the L-PRF. It can play an important role in regenerative procedures.

Ding, Z.-Y., Tan, Y., Peng, Q., et al. (2021) - Platelet concentrates such as PRF, PRP and CGF have become popular in recent years for their use in soft and hard tissue regeneration. There are multiple factors in such platelet aggregates that regulate wound healing. Tae-Hoon Kim evaluated the effect of platelet concentrates on bone healing and found significant bone formation. The effect of PRP, PRF, and CGF was similar and it was suggested that they can be used for successful bone grafting. The reparative protocols introduced in the present review focus on the application of platelet concentrates in several forms, either lyophilized or blended with (bio)materials (chitosan, silk fibrin, metal nanoparticles, mineral trioxide aggregate graft materials and hydroxyapatite) and/or stem cells [adipose-derived stem cells, bone marrow stromal cells (BMSC) and human dental pulp cells] or those modulated with drugs (antagonism and synergism) to enhance tissue regeneration.

Jaswal, T., & Gupta, J. (2021) - recognized the widespread use of SNP due to their distinct antibacterial abilities. The paper analyzed the toxic effects of SNPs on human health. Additionally, it studied the extent to which, the silver ion fraction contributes to cell toxicity. It was shown, through in vivo evaluations, that sizes between 10 to 100 nm and concentration in the range of 5 to 10mg/mL is very toxic to mitochondria. studies shows that nanoparticles can pass the cell membranes and also interact with the biological system due to the strong oxidative activity[5] silver nanoparticles (AgNPs) after passing the cell membranes and release ther ions of silver into the cell these ions has side effects on the biological system these ions induced genotoxicity[6] ,cyctotoxicity[76] and even death of the cell.

Description of Broad Area

The major limitation for host derived scaffolds from autologous platelets is lack of strength and antimicrobial property. The study addresses to overcome these limitations by incorporation of nanoparticles in advanced autologous platelet product. The concentrated growth factor is advanced autologous product used for bone and soft tissue repair in various surgeries. The idea isto enhance the bone formation and antimicrobial properties of CGF with the nanoparticles incorporation . The prepared novel product as compared to traditional ones will possess improve mechanical, bone formation and antimicrobial properties for immediate autologous use and economical option as compared to bone graft and barrier membranes.

OBJECTIVES OF THE STUDY

1. Preparation and characterization of concentrated growth factor & platelet rich fibrin from venous blood of the donor.
2. Preparation and characterization of nanoparticle - Ag suspension
3. Incorporation of nanoparticle - Ag suspension into concentrated growth factor and characterization of novel scaffold.
4. To check the cytotoxic and antimicrobial potential of novel scaffold.

METHODOLOGY

The study will be conducted according to ethical guidelines, approved by Institutional Ethical Committee (IEC), Faculty of Dental sciences, Manav Rachna Dental College.

Research setting

The research will be performed in Department of Conservative Dentistry and Endodontics, Manav Rachna Dental college, Faridabad in collaboration with Jamia Millia Islamia, New Delhi after obtaining the clearance from the Institutional Ethical Committee (IEC).

Single patient from which every time blood will be taken. {10 to 20 ml at one time. (total 60 to 80 ml blood for whole experiment)}

INCLUSION CRITERIA (FOR PI TO DONATE BLOOD)

1. Patient should be healthy adult of age group 25- 40 years of either gender
2. Patient should be absent from infectious (HIV, Hepatitis B) and blood diseases (thrombocytopenia)
3. Patient with no history of medication that may interfere with platelet function in the past 3months. (for example, aspirin)

The platelet count of the volunteer's blood should be in the normal limits i.e 1.5 to 4.5 lakhs per ml of blood.

CGF Preparation:

CGFs will be produced as follows: 20 mL of blood sample will be collected from each volunteer and evenly divided into two centrifuge tubes, respectively for fresh PRF and CGF. These tubes will be immediately centrifuged in a special machine (Labomed centrifuge machine). The tubes will be centrifuged with one step centrifugation protocol: 30sec -acceleration, 2min - 2700 rpm, 4min - 2400 rpm, 4min - 2700 rpm, 3min - 3000 rpm, 36sec – deceleration and stop. At the end of the process, three blood fractions were obtained. The middle part is the CGF glue which will be removed and membrane will be formed by squeezing the glue in between two pieces of sterile gauze pieces (Qiao et al., 2016; Upadhayaya et al., 2017).

Preparation of Nanoparticle

Rationale: The rationale behind preparation of **nAg suspension** is Obtaining a standardized reproducible preparation for all samples in the size range of 5-10 nm

Nanoparticle Preparation In this project we are planning to synthesize nAg particles in the Nano-dimensions, by applying the chemical reduction method using poly ethylene glycol ortrisodium citrate

The prepared nAg particles will be mixed with compatible media, will be poured into the tube and sonicated at 200 W for 2 minutes in a sonicator device. For new scaffold the centrifugation processwill be same as described above except the 9ml of blood will be mixed with I ml of n Ag suspension. Other method to incorporate is ulrasonification method. The characterization techniques will be applied to characterize the samples with SEM (Scanning electron microscopy). The effect of nano-particles on the release of growth factors will be determined by Elisa

The cytotoxicity test will be performed on human cell lines using MTT and cell viability assay. The microbiological aspect will be determined against most common aerobic (streptococcus viridans) and anaerobic bacteria (prevotella/ porphyromonas species) of oral cavity surgical site by one of inhibition test. All the experiments will be performed in triplicates
10 to 20 ml of blood at one time will be taken from the same donor. (total 60 to 80 ml blood for whole experiment)

EXPECTED OUTCOME OF THE RESEARCH

A novel CGF incorporated with silver nanoparticles scaffold with improved properties will be obtained.

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DEVELOPMENT AND PHYSICAL CHARACTERIZATION OF A NOVEL BIODEGRADABLE SCAFFOLD WITH GROWTH FACTORS AND NANO PARTICLES

by Alpa Gupta

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Researcher : Dr. Alpa gupta Registration Number : 21/PHD/030

Supervisor: Dr. Arundeep Singh Department: Conservative Dentistry & Endodontics

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Research Scholar Research Supervisor

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DEVELOPMENT AND PHYSICAL CHARACTERIZATION OF A NOVEL BIODEGRADABLE SCAFFOLD WITH GROWTH FACTORSAND NANO PARTICLES

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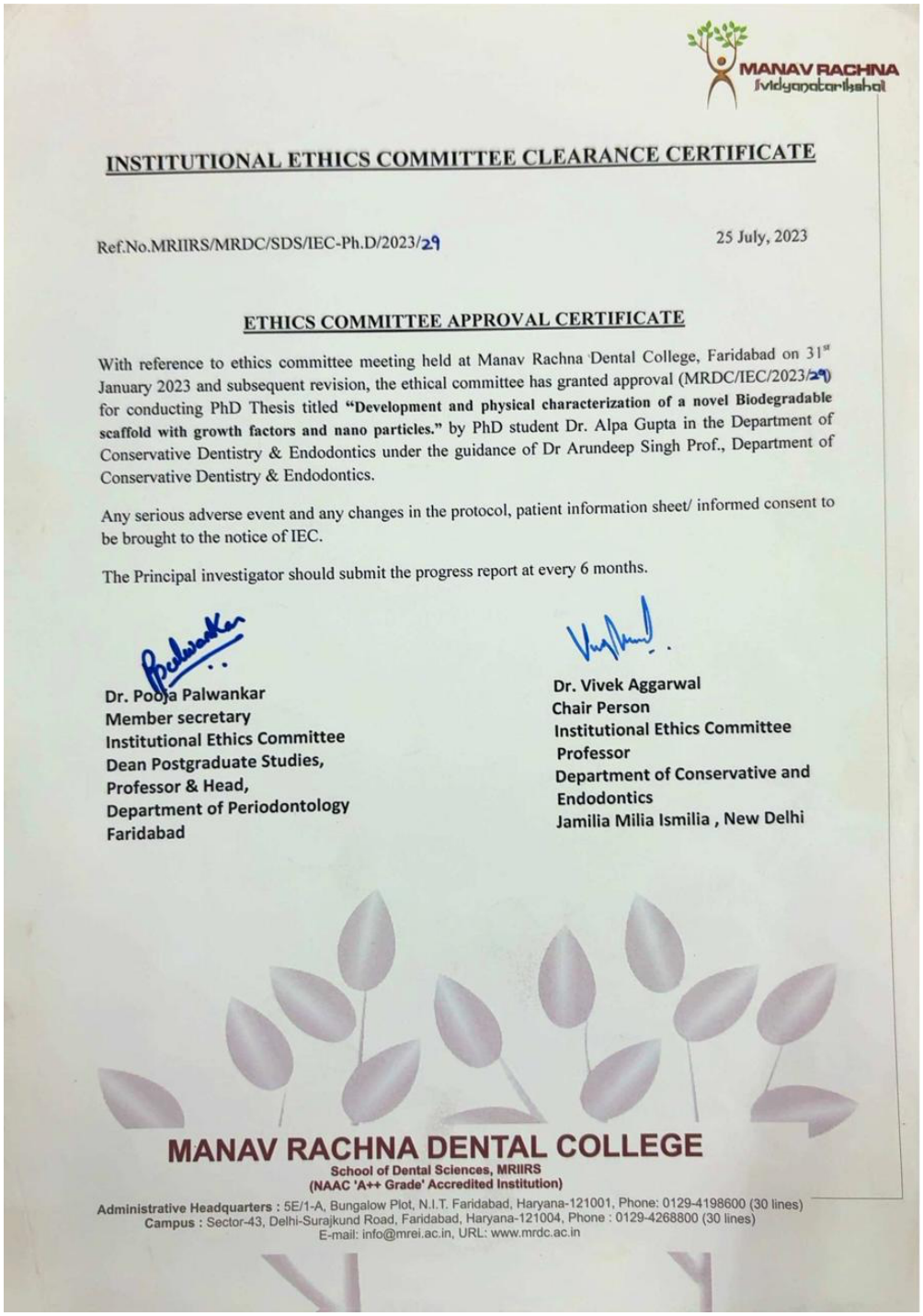

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Vidyanatarikshal

INSTITUTIONAL ETHICS COMMITTEE CLEARANCE CERTIFICATE

Ref.No.MRIIRS/MRDC/SDS/IEC-Ph.D/2023/29

25 July, 2023

ETHICS COMMITTEE APPROVAL CERTIFICATE

With reference to ethics committee meeting held at Manav Rachna Dental College, Faridabad on 31st January 2023 and subsequent revision, the ethical committee has granted approval (MRDC/IEC/2023/29) for conducting PhD Thesis titled **"Development and physical characterization of a novel Biodegradable scaffold with growth factors and nano particles."** by PhD student Dr. Alpa Gupta in the Department of Conservative Dentistry & Endodontics under the guidance of Dr Arundeep Singh Prof., Department of Conservative Dentistry & Endodontics.

Any serious adverse event and any changes in the protocol, patient information sheet/ informed consent to be brought to the notice of IEC.

The Principal investigator should submit the progress report at every 6 months.

Dr. Pooja Palwankar
Member secretary
Institutional Ethics Committee
Dean Postgraduate Studies,
Professor & Head,
Department of Periodontology
Faridabad

Dr. Vivek Aggarwal
Chair Person
Institutional Ethics Committee
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MANAV RACHNA DENTAL COLLEGE, FACULTY OF DENTAL SCIENCES
MRIIRS PROTOCOL FOR IEC CLEARANCE

1. Full Title of Study	DEVELOPMENT AND PHYSICAL CHARACTERIZATION OF A NOVEL BIODEGRADABLE SCAFFOLD WITH GROWTH FACTORS AND NANO PARTICLES
2.1 Name and signatures of the candidate 2.2 Department 2.3 Degree/ Course 2.4 Batch of admission to course 2.5 Month & Year of submission of thesis	2.1 Alpa Gupta Signature 2.2 Conservative Dentistry and Endodontics 2.3 PhD 2.4 2021 Summer 2.5 2024
Name of Faculty & Department (Guide/ Co-Guide) Dr Arundeep Singh (Guide) Dr Vivek Aggarwal (Co-Guide)	Signatures (Guide/ Co-Guide) 3.1 3.2
4.Objectives of the study	4.1 To prepare and characterize the concentrated growth factor and platelet rich fibrin from venous blood of the donor. To prepare and characterize the nanoparticle- nAg suspension To check the cytotoxic and antimicrobial potential of novel scaffold
5.Why is this study required? Provide brief justification	To enhance the bone formation and antimicrobial properties of CGF with the nano-particles incorporation The prepared novel product as compared to traditional ones will possess improved mechanical bone formation and antimicrobial properties for immediate autologous use and economical option as compared to bone graft and barrier membranes without host rejection
6.Methodology	Number of the patients: Single patient from which every time will be taken. {10 to 20 ml at one time (total 60 to 80ml for whole experiment)} Inclusion Criteria Patient should be healthy adult of age group 25-40 years of either gender Patient should be absent from infectious (HIV,

	Hepatitis B) and blood diseases (Thrombocytopenia) Patient without taking any medicine (aspirin) which may affect the function of platelet The platelet count of the volunteer venous blood should be in the normal limits i.e. 1.5 lakh to 4.5 lakh per ml of blood. 6.3 Exclusion Criteria 1. Patient having any infectious and blood diseases 2. Patient taking any medicine which may affect the function of platelet or blood. 3. Patients having abnormal blood count. 6.4 Study Design The study will be conducted according to ethical guidelines, approved by Institutional Ethical Committee (IEC), Faculty of Dental CGF Preparation: The tubes will be centrifuged with one step centrifugation protocol: 30sec -acceleration, 2min - 2700 rpm, 4min - 2400 rpm, 4min - 2700 rpm, 3min - 3000 rpm, 36sec – deceleration and stop Preparation of Nanoparticle - n Ag suspension Rationale: The rationale behind preparation of n standardized reproducible preparation for all samples in the size range of 5-10 nm Nano particle Preparation &incorporation In this project we are planning to synthesize nAg particles in

	the Nano-dimensions, by applying the chemical reduction method using poly ethylene glycol or trisodium citrate The prepared nAg particles will be mixed with compatible media, will be poured into the tube and sonicated at 200 W for 2 minutes in a sonicator device. For new scaffold the centrifugation process will be same as described above except the 9ml of blood will be mixed with I ml of n Ag suspension. Other method to incorporate is ulrasonification method. The characterization techniques will be applied to characterize the samples with SEM (Scanning electron microscopy). The effect of nano particles on the realease of growth factors will be determined by Elisa. Cytotoxicity & Antimicrobial assays The cytotoxicity test will be performed on human cell lines using MTT and cell viability assay. The microbiological aspect will be determined against most common aerobic (streptococcus viridans) and anaerobic bacteria (prevotella/ porphyromonas species) of oral cavity surgical site by one of inhibition test. All the experiments will be performed in triplicates.
7. Permission from Drug Controller General of India (DCGI)	1. Required 2. Not required 3. Received 4. Applied when: ✔
8. Permission from DGFT , if required	1. Required 2. Not required 3. Received 4. Applied when: ✔

a) Safety measures for proposed interventions Results of relevant laboratory tests Result of studies in human	a) Standard Laboratory protocols to be followed b) A novel CGF incorporated with nanoparticles scaffold with improved properties in terms of mechanical, antimicrobial, biocompatibility and healing will be obtained.
10. Plans to withdraw standard therapy in research	Yes ✓ No Remarks:
11. Plan for provision of coverage for medical risk	NA
12. How you will maintain Confidentiality of subject?	NA
13. Costs Involved (Appx. in Rs.) Investigations Disposables Implants Drugs / Contrast Media Who will bear the costs of the requirements? (mark √)	Rs 70000-1.2 lakhs 1. Patient 2. Protocol 3 Exempted 4. Other Agencies (Name) Self
14. Participant Information Sheet (mark √ if yes)	✓ Attached English ✓ version Attached Hindi version Certified that Hindi version is a true translation of English version
15. Participant Informed Consent Form (mark √ if yes)	Attached ✓ English version Attached Hindi version

	Certified that Hindi version is a true translation of English version
16. Whether any work on this Protocol has started or not?	(mark √ if yes, X if no) X (no work has been started on this protocol) (Please enclose a separate certificate to this effect). A certificate stating that no work has been carried out has been attached
17.Attached documents (If any)	17.1 IEC clearance will be provided

PARTICIPANT INFORMED CONSENT FORM (PICF)

Protocol / Study number:

Participant identification number for this trial:
Title of project: Development and physical characterization of a novel biodegradable scaffold with growth factors and nano particles-
Name of Principal Investigator: ALPA GUPTA Tel.No(s). 9050312010

The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.
The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand thatmy participation is voluntary and that I am free to withdraw at any time, without giving anyreason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from Department of Conservative Dentistry and Endodontics, Manav Rachna Dental College. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

Date:

(Signatures/ Left Thumb Impression)

Pla
ce:

Name of the Participant: Son / Daughter / Spouse of:

This is to certify that the above consent has been obtained in my presence.

_____

Signatures of the Principal Investigator Date:
Place:

1) Witness – 1

_____

Signatures
Name:
Address:

2) Witness – 2

_____

Signatures
Name:
Address:

प्रतिभागी सूचित सहमति प्रपत्र (PICF)

प्रोटोकॉल / अध्ययन संख्या:

इस परीक्षण के लिए प्रतिभागी पहचान संख्या: विकास कारकों और नैनो कणों के साथ एक उपन्यास बायोडिग्रेडेबल पाड़ का विकास और भौतिक चारेक्टराइजेशन

परियोजना का शीर्षक: प्रधान अन्वेषक का नाम: अल्पा गुप्ता
दूरभाष सं. 9050312010

प्रदान की गई सूचना पत्रक की सामग्री को मेरे द्वारा ध्यान से पढ़ा गया है / मुझे विस्तार से समझाया गया है, जिस भाषा में मैं समझता हूं, और मैंने सामग्री को पूरी तरह से समझ लिया है। मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।
अध्ययन की प्रकृति और उद्देश्य और इसके संभावित जोखिम / लाभ और अध्ययन की अपेक्षित अवधि, और अध्ययन के अन्य प्रासंगिक विवरण मुझे विस्तार से बताए गए हैं। मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मैं बिना कोई कारण बताए, मेरी चिकित्सा देखभाल या कानूनी अधिकार को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

मैं समझता हूं कि इस शोध में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे किसी भी मेडिकल नोट के अनुभागों को कंजर्वेटिव डेंटिस्ट्री एंड एंडोडोंटिक्स विभाग, मानव रचना डेंटल कॉलेज के जिम्मेदार व्यक्तियों द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंच की अनुमति देता हूं।

प्रधान अन्वेषक के हस्ताक्षर दिनाक: स्थान:

1) गवाह - 1

हस्ताक्षर

नाम

2) गवाह - 2

हस्ताक्षर

नाम:

PATIENT INFORMATION SHEET (PIS)

Study Title: Development and physical characterization of a novel biodegradable scaffold with growth factors and nano particles

You are invited to participate in a research study conducted by me who is conducting research under the Manav Rachna International University, Faridabad, Haryana.

The aim of the study is to develop and physically characterize a novel biodegradable scaffold with growth factors and nano particles
Once the inclusion criteria are satisfied the blood samples will be taken at different levels of experiment
Your participation will be voluntary. There is no anticipated risk/discomfort.
Your identity/data will remain confidential and protected under all circumstances and will not be used without your prior permission. The information collected from you in any form, will be used in a coded manner.
Incase during the conduct of the research any injury per se occurs the treatment shall be carried out free of cost in the college.
Compensation of subjects for disability or death resulting from such injury: NA
You are free to withdraw from the research at your own will during the conduct of the research.
Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned: 10 to 20 ml at one time.(total 60 to 80 ml blood for whole experiment)
Cost of ELISA kit: Rs. 70000-80000
Cost of cytotoxicity and antimicrobial assay- 30000-40000.

In case of drug trials: a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned b) Initial Bio equivalent study of the drug / references should be provided: NA
I hereby state that translation to vernacular is accurate
Statement that there is a possibility of failure of IP to provide intended therapeutic effect: NA
Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect: NA
Donor has the right to ask the investigator to destroy or withdraw the sample
Signature and Address of Patient Signature of Guide with date Signature of Researcher

Dr. Alpagupta
Research Scholar,
Dept. of Conservative Dentistry and Enododontics
, Manav Rachna Dental College.
(9050312010)
E-mail Id: alpagupta2008@gmail.com

रोगी सूचना पत्रक (पीआईएस)

अध्ययन का शीर्षक: विकास कारकों और नैनो कणों के साथ एक नए बायोडिग्रेडेबल मचान का विकास और भौतिक लक्षण वर्णन

आप सभी को मेरे द्वारा किए गए शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जाता है, जो मानव रचना अंतर्राष्ट्रीय विश्वविद्यालय, फरीदाबाद, हरियाणा के अंतर्गत अनुसंधान कर रहा है।

अध्ययन का उद्देश्य विकास कारकों और नैनो कणों के साथ एक नए बायोडिग्रेडेबल मचान को विकसित करना और उसका भौतिक रूप से लक्षण वर्णन करना है। एक बार जब समावेशन मानदंड संतुष्ट हो जाते हैं तो प्रयोग के विभिन्न स्तरों पर रक्त के नमूने लिए जाएँगे। आपकी भागीदारी स्वैच्छिक होगी। कोई प्रत्याशित जोखिम/परेशानी नहीं है। आपकी पहचान/डेटा सभी परिस्थितियों में गोपनीय और संरक्षित रहेगा और आपकी पूर्व अनुमति के बिना इसका उपयोग नहीं किया जाएगा। किसी भी रूप में आपसे एकत्रित की गई जानकारी का उपयोग कोडित तरीके से किया जाएगा। यदि शोध के संचालन के दौरान कोई चोट लगती है तो कॉलेज में उपचार निःशुल्क किया जाएगा।

ऐसी चोट के कारण विकलांगता या मृत्यु के लिए विषयों का मुआवजा: NA

आप शोध के दौरान अपनी इच्छा से शोध से हटने के लिए स्वतंत्र हैं।

रक्त के नमूने की मात्रा, चम्मच भर में, बताई जानी चाहिए: एक बार में 10 से 20 मिली। (पूरे प्रयोग के लिए कुल 60 से 80 मिली रक्त)

एलिसा किट की लागत: रु. 70000-80000

साइटोटॉक्सिसिटी और एंटीमाइक्रोबियल परख की लागत- 30000-40000।

दवा परीक्षणों के मामले में: क) दवा का रासायनिक नाम, इसके निर्माण की तिथि और बैच संख्या का उल्लेख किया जाना चाहिए ख) दवा का प्रारंभिक जैव समतुल्य अध्ययन / संदर्भ प्रदान किए जाने चाहिए: एनए

मैं यह घोषणा करता हूं कि स्थानीय भाषा में अनुवाद सटीक है

बयान कि आईपी के इच्छित चिकित्सीय प्रभाव प्रदान करने में विफलता की संभावना है: एनए

बयान कि प्लेसबो नियंत्रित परीक्षणों के मामले में, विषयों को प्रशासित प्लेसबो का कोई चिकित्सीय प्रभाव नहीं होगा: एनए

दाता को जांचकर्ता से नमूना नष्ट करने या वापस लेने के लिए कहने का अधिकार है

रोगी का हस्ताक्षर और पता गाइड के हस्ताक्षर दिनांक के साथ शोधकर्ता के हस्ताक्षर

डॉ. अल्पगुप्ता रिसर्च
स्कॉलर,

कंजर्वेटिव डेंटिस्ट्री और एनोडोडोंटिक्स विभाग,
मानव रचना डेंटल कॉलेज।
(9050312010)
ईमेल आईडी: alpagupta2008@gmail.com